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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,952	01/20/2006	Kazuya Tanaka	050246	4301
23850 7590 10/20/2009 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005				
EXAMINER				
LACLAIR, DARCY D				
ART UNIT		PAPER NUMBER		
1796				
MAIL DATE		DELIVERY MODE		
10/20/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/531,952

**Applicant(s)**

TANAKA ET AL.

**Examiner**

Darcy D. LaClair

**Art Unit**

1796

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/ISD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 1/7/2009.

### DETAILED ACTION

1. All outstanding rejections, except for those maintained below are withdrawn in light of the response filed on **6/9/2009**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following action is properly made **FINAL**.

### *Terminal Disclaimer*

2. The terminal disclaimer filed on 6/9/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of **copending application no 10/551,872** has been reviewed and is accepted. The terminal disclaimer has been recorded.

### *Claim Rejections - 35 USC § 103*

3. **Claims 2 and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bastioli et al. (WO 02/059199)** in view of **Kanamori et al. (US 6,262,184)** with **evidence** provided by the **Showa Product Data page for Bionolle (2007)**.

The rejection is adequately set forth in **paragraph 3** of the office action mailed **1/2/2009**, and is incorporated here by reference.

4. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Bastioli et al. (WO 02/059199)** in view of **Kanamori et al. (US 6,262,184)** with **evidence**

provided by the **Showa Product Data page for Bionolle (2007)**, further in view of **Wypych (2000)** (pages as indicated below).

The rejection is adequately set forth in **paragraph 4** of the office action mailed **1/2/2009**, and is incorporated here by reference.

5. **Claims 4-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bastioli et al. (WO 02/059199)** in view of **Kanamori et al. (US 6,262,184)** with **evidence** provided by the **Showa Product Data page for Bionolle (2007)**, further in view of **Downie et al. (US 2001/0027225)**

The rejection is adequately set forth in **paragraph 5** of the office action mailed **1/2/2009**, and is incorporated here by reference.

6. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Bastioli et al. (WO 02/059199)** in view of **Kanamori et al. (US 6,262,184)** with **evidence** provided by the **Showa Product Data page for Bionolle (2007)**, further in view of **Akao et al. (US 5,814,497)**

The rejection is adequately set forth in **paragraph 6** of the office action mailed **1/2/2009**, and is incorporated here by reference.

7. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Bastioli et al. (WO 02/059199)** in view of **Kanamori et al. (US 6,262,184)** with **evidence**

provided by the **Showa Product Data page for Bionolle (2007)**, further in view of **Obuchi et al. (US 6,916,950)**

The rejection is adequately set forth in **paragraph 7** of the office action mailed **1/2/2009**, and is incorporated here by reference.

### ***Response to Arguments***

8. Applicant's arguments filed **6/9/2009** have been fully considered. Specifically, applicant argues

**(A)** The rejection over Claims 1-3 of **copending application no. 10/551,872** has been obviated by the filing of a terminal disclaimer over **USSN 10/551,872**,

**(B)** The Examiner states that Bastioli WO'199 discloses a mixture of (A) an aromatic-aliphatic polyester, (B) an aliphatic polyester, and (C) a polylactic acid polymer, which generally corresponds to components (B), (C), and (A) in Claim 2; With regard to the compositional ratios, the examiner states that Bastioli does not disclose the compositional ratios of the components in Claim 2; in particular the lactic acid content in Bastioli is below the range of 70-90 mass% required by claim 2; Kanamori is cited as disclosing a biodegradable resin comprising polylactic acid and aliphatic polyester carbonate in a ratio of 95/5 to 5/95; Bastioli discloses a composition with (A) an aromatic-aliphatic polyester, (B) an aliphatic polyester, and (C) a polylactic acid polymer, and discloses that (A+B) is 40-70% and (C) is 6-30%, which would correspond in the claim to (A) the lactic acid based resin being 6-30% and the sum of (B+C) being 40-70%; The claim requires (A+B) are present in 90-70%, while (B) is present at 5-25%,

which would inherently limit the lactic acid based resin to at least 45%, well above the 30% maximum in Bastioli; the rejection is based on modifying Bastioli based on Kanamori's teachings to optimize Bastioli, however Bastioli is already "optimized" for its given component combination; and very clearly teaches polylactic acid at 6-30%, and applying the modifications proposed would require an enormous modification away from the range taught in Bastioli; Furthermore, the Bastioli invention is clearly based on ternary mixtures, and these effects are surprising relative to binary systems; Kanamori's results are based on a binary system of polylactic acid and aliphatic polyester carbonate, therefore there is no modification based on Kanamori to modify Bastioli;

(C) The rejection of Claims 3, 4-5, 6, and 8 are based on a combination of Bastioli and Kanamori, discussed above.

9. **With respect to argument (A)**, applicant's arguments have been considered and are **persuasive**. The obviousness type double patenting rejection over of **copending application no. 10/551,872** is withdrawn in view of the terminal disclaimer filed on **6/9/2009**.

**With respect to argument (B)**, applicant's arguments have been considered but are **not persuasive**. While it is noted that Bastioli teaches polylactic acid between 6 and 30% by weight in the appendix and claims, there is no teaching against adjusting the content of polylactic acid to a higher content. In fact, only low content of polylactic acid is taught against in the specification. (See p. 9 paragraph 4) Furthermore, Bastioli goes outside the concentrations recited in the abstract in the Examples. For example,

in example 7, which is an inventive example, and not a comparative example, Bastioli teaches 40% polylactic acid (C), 20% aromatic-aliphatic polyester (A), and 40% aliphatic polyester (B). (See p. 16, Table 1) Contrary to applicant's assertion that Bastioli is "very clear" on limiting the range from 6-30% polylactic acid, Bastioli provides examples which fall outside of this range in the inventive examples. This makes it clear to one of ordinary skill in the art that while a range of 6-30% is claimed, variations are possible. Furthermore Bastioli teaches up to 5% of plasticizers, (see p. 9 par 5) as well as other additives such as polymers (see p. 12 par 3) which suggests that the compositional ranges will maintain their benefits even in the face of adjustments. Applicant's requirements are for

A+B = 70% to 90%, B = 5% - 25%, C = 10% to 30%

Therefore, A = 55% to 85%

The example 7 in Table 1, discussed above, falls within applicant's required range (20%) for the content of aromatic-aliphatic polyester (B) as well as for the polylactic acid polymer and aliphatic polyester (A+B), (80%) and is only 10-15% high or low in the case of aliphatic polyester and polylactic acid polymer, respectively.

Bastioli specifically teaches against increasing the concentrations of the aliphatic-aromatic polyester (A), or the aliphatic polyester (B). (See p. 9 pars 2,3) Bastioli does not, however, teach against increasing the concentration of the lactic acid resin above that specifically taught. Rather, Bastioli teaches only that concentrations below 5% of the polylactic acid resin will have no effect on the balance of tearing properties or adjustment of the modulus. (See p. 9 par 4) Additionally, this teaching points out that

polylactic acid resin affects the tearing properties and the modulus. Specifically, to achieve a concentration in the range required by applicant, the polylactic acid would be increased, and the aliphatic polyester would be decreased. *This is not precluded by the disclosure of Bastioli.*

Kanamori teaches a biodegradable resin composition comprising polylactic acid and aliphatic polyester carbonate in a ratio of 95/5 to 5/95, or comprising *mainly* polylactic acid and aliphatic polyester and/or aliphatic polyester carbonate. (See abstract) It is noted that the composition of Kanamori discloses a polylactic acid and an aliphatic polyester **and**/or an aliphatic polyester carbonate, which is a ternary mixture having a polylactic acid and two polyesters. Kanamori teaches that a high ratio of polylactic acid will give a high tensile strength and flexural strength. Decreasing the aliphatic polyester component can also affect the degree of biodegradability and the transparency. (See col 6 line 37-49) Table 1 demonstrates that the degree of biodegradability is reduced as the ratio of polylactic acid resin is increased, and the tensile strength and flexural strength are also increased as the ratio of lactic acid resin is increased toward 90 (or 90%). (See col 10 line 42-65) This demonstrates that the content of polylactic acid based resin is a results effective variable, and can be optimized within a ternary system involving a polylactic acid and two polyesters. See MPEP § 2144.05 (B). Case law holds that “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Given that Kanamori teaches benefits of increasing the content of polylactic acid, and the disclosure of Bastioli does



not preclude adjustments in the polylactic acid, it would be obvious to one of ordinary skill in the art, particularly specifically in the area of biodegradable resin compositions, given the teaching of Kanamori, to adjust the ratio of poly lactic acid resin in the composition of Bastioli in order to obtain a resin which has an increased flexural strength and tensile strength for applications in which that is desirable. Based on the teachings of Kanamori, one of ordinary skill in the art would arrive at a composition having a higher level of lactic acid based resin consistent with applicant's claimed range.

**With respect to argument (C)**, applicant's arguments have been considered but are **not persuasive**. Attention is directed to the discussion of argument (B), above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darcy D. LaClair whose telephone number is (571)270-5462. The examiner can normally be reached on Monday-Friday 8:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darcy D. LaClair  
Examiner  
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/DDL/

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